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Customer Number

Patent
Case No.: 59698US002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Inventor: HENDERSON, CHRISTOPHER P.

Application No.: 10/810958 Confirmation No.: 9828

Filed: March 26, 2004

Title: NON-ELASTOMERIC RESPIRATOR MASK THAT HAS DEFORMABLE CHEEK PORTIONS

PETITION TO THE DIRECTOR UNDER 37 CFR § 1.181

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

CERTIFICATE OF TRANSMISSION [37 CFR § 1.8(a)]

I hereby certify that this correspondence is being transmitted to United States Patent and Trademark Office on the date shown below via the Office electronic filing system.

October , 2008
Date


Signed by: Susan M. Dacko

Dear Sir:

This Petition is taken in response to the Final Office Action dated December 12, 2007.

Fees

- It is believed that no fee is due; however, in the event a fee is required, please charge the fee to Deposit Account No. 13-3723.

I. STATEMENT OF FACTS

On September 23, 2008, the Examiner rejected applicants' pending claims 1 and 3-34. In addition to making prior art rejections, the Examiner also objected to applicants' specification under 35 USC § 132(a) for introducing new matter into the specification. As originally filed, applicants' specification included the following definitions for "mask body" and "rigid insert":

"Mask body" means a structural member that is configured to fit over a person's nose and mouth and that helps define an interior gas space separate from an exterior gas space;

"Rigid insert" refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant portion that makes contact with and generally conforms to a wearer's face; and

Applicants later amended these definitions to read as follows (see May 24, 2007 Amendment), where the underlined text is the newly-introduced language:

"Mask body" means the part(s) of a respiratory mask that extends in spaced relation away from a wearer's face during use and over their a structural member that is configured to fit over a person's nose and mouth to help and that helps define an interior gas space that is separate from an exterior gas space;

"Rigid insert" refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant mask body part portion that makes contact with and generally conforms to a wearer's face; and

The Examiner presently holds that the following bolded language in the definition constitutes new matter:

"Mask body" means **the part(s) of a respiratory mask that extends in spaced relation away from a wearer's face during use and over their** nose and mouth to help define an interior gas space that is separate from an exterior gas space;

"Rigid insert" refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant **mask body part** that makes contact with and generally conforms to a wearer's face; and

Applicants have taken issue with the Examiner's conclusion that the bolded language is new matter.

II. POINTS TO BE REVIEWED

Applicants request that the Director rule on the issue of whether the bolded language presented above constitutes new matter.

III. ACTION REQUESTED

Applicants request that the Director reverse the Examiner's position that the above-noted bolded text is new matter and instruct the Examiner to withdraw this objection.

IV. MEMORANDA IN SUPPORT OF APPLICANTS' POSITION

In 1836 the Supreme Court first noted that the right to alter a patent application did not include the right to introduce "a distinct and different invention" "not contemplated by the specification, as submitted at the outset."¹ In 1952 Congress codified this rule with the enactment of 35 USC § 132. This statutory provision provides that "[n]o amendment shall introduce new matter into the disclosure of the invention." In considering 35 USC § 132, the reviewing authorities have made a number of interpretations. In particular, the Courts have indicated that an amendment to the specification does not violate the new matter rule if it merely "clarifies or completes" the original disclosure.² Thus, the specification and drawings may be amended to conform to one another.³ Further, the Court of Customs and Patent Appeals, the predecessor to the United States Court of Appeals for The Federal Circuit, has stated that when "the amendments to the specification merely render explicit what had been implicitly disclosed originally, and, while new language has certainly been added, we are not prone to view all 'language' ipso facto as 'new matter'".⁴ Thus, while new language that has been added to the specification often is, as stated, "new" the new language is not necessarily "new matter" prohibited by 35 USC § 132.⁵

On a number of occasions, the reviewing courts have indicated that an applicant's invention disclosure includes both the drawings submitted with the application on filing and the claims and the specification. The Courts accordingly have found that there is no new matter bar to amendments that make the specification conform to the subject matter disclosed in the original drawings and claims or vice versa. As noted in *Tektronix Inc v. The United States*, an applicant can, by amendment, make "explicit a disclosure which was implicit in the application as filed."⁶

¹ *Godfrey v. Eames*, 68 US 317, 325 (1864)

² *Tektronix Inc v. The United States*, 445 F.2d 323, 326-27, 165 USPQ 392, 394 (Ct. cl. 1971), *appeal after remand*, 575 F.2d 832, 198 USPQ 378 (Court of Claims 1978), cert denied, 439 US 1048 (1978) ("In essence, what the applicant did was amend the drawing and specification in response to queries by the patent examiner, and thereby simply made explicit disclosure which was implicit in the application as filed."); *Helms Products v. Lakeshore Manufacturing Company*, 227 F.2d 677, 679, 107 USPQ 313, 314 (7th Circuit 1955) ("Amendments to the specification for the purpose of clarity and definiteness are permissible.").

³ *In re Heinle*, 342 F.2d 1001, 1007, 145 USPQ 131, (CCPA 1965).

⁴ *In re Wright*, 343 F.2d 761, 767, 145 USPQ 182, 188 (CCPA 1965).

⁵ *In re Oda*, 443 F.2d 1200, 170 USPQ 268, 271 (CCPA 1971) ("In a sense, anything inserted in a specification that was not there before is new to the specification but that does not necessarily mean it is prohibited 'new matter.'").

⁶ *Tektronix*, 165USPQ at 394.

Applicants have amended the definition of mask body to be the following:

The parts of a respiratory mask that extends in spaced relation away from a wearer's face during use and over their nose and mouth to help define an interior gas space that is separate from an exterior gas space.

Support for this definition can be found in the original specification at page 3, lines 29-31 and page 4, lines 8-12 and in Figures 1-3 and at pages 5-9 and 11-13. In particular, page 5, lines 9-10 describes a "mask 10 [that] fits over a wearer's nose and mouth but not over their eyes, and hence is often referred to as a 'half-mask'." Further, FIGs. 2 and 3 show a mask body 12 that is configured to extend in spaced relation away from the wearer's face during use. The original definition of mask body further indicates that the mask body is a structural member that is configured to fit over a person's nose and mouth to help define an interior gas space separate from an exterior gas space. In view of the drawings, the description in the specification, and the language used in the original definitions, applicants submit that the present definition of mask body does not constitute new matter.

The revised definition of rigid insert also does not contain new matter. That revised definition is reproduced below for ease of reference:

"Rigid insert" refers to a relatively stiff structural member that has been used on respiratory masks to provide adequate structure for attaching fluid communication components such as filter cartridges and exhalation valves while being joined to a more compliant mask body part that makes contact with and generally conforms to a wearer's face; and

Support for the language used in the definition of rigid insert can be found on page 1 of the specification at lines 17-31 and in the original definition at page 4, lines 19-22. Applicants have only changed the term "portion" to "mask body part". The new language "mask body part" merely improves upon the original "portion" wording. As such, applicants fail to understand how the revised definition of rigid insert could constitute new matter.

Accordingly, applicants' amendment to the definitions of mask body and rigid insert has only made explicit what has been otherwise already disclosed in the specification and drawings as filed. For this reason, applicants submit that the objection to these modified definitions are not modifications that would constitute new matter under the terms of 35 USC § 132.

Accordingly, applicants request that the Commissioner respectfully grant this petition.

This Petition is being filed within two months of the issuance of the Office Action dated September 23, 2008.

Respectfully submitted,

October 2 , 2008

Date

By: 
Karl G. Hanson, Reg. No.: 32,900
Telephone No.: 651-736-7776

Office of Intellectual Property Counsel
3M Innovative Properties Company
Facsimile No.: 651-736-3833